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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR *	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,960	09/15/2003	Leslie S. Feinberg	030716	1119

7590 05/18/2005
Carl D. Crowell
P.O. Box 923
Salem, OR 97308

EXAMINER

GILBERT, SAMUEL G

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/662,960	Applicant(s) FEINBERG, LESLIE S.	
	Examiner Samuel G. Gilbert	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/15/2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the subject and the practitioner as the same person, as in claim 9, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The applicant argues that Figure 1 is fully representative of all the claims. The examiner disagrees. Figure one depicts a patient and a practitioner and claim 9 calls for the patient and practitioner to be one and the same. No one looking at Figure 1 would conclude that the method as claimed could be performed on oneself with the patient acting as the practitioner.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary,

the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention fails to produce a useful, tangible, concrete result in the technological arts.

In analyzing claim 1 for patent eligible subject matter, it is useful to first answer the question "What did applicant[s] invent?" In re Abele, 214 USPQ 682 (CCPA 1982). The preamble of claim 1 characterizes the invention as an "energetic based health care method" A careful review of the disclosure reveals that the applicant's invention can best be described as a procedure or methodology by which a person suffering from dysfunction may seek relief. It is clear from the scope of the disclosure and the claims

that no specific technology is employed in the process. Rather, what is set forth is a rather general procedure with the stated intention of helping a person correct a dysfunction.

The invention thus understood must be analyzed under the prevailing case law. The statute itself allows for the patenting of processes. However, it has been determined in many contexts that not all processes set forth patent eligible subject matter. In other words, it must always be determined whether a particular invention ostensibly falling within one of the enumerated statutory categories is in fact something for which the patent statutes were designed. A primary test that has recently been applied is whether the invention produces a useful, concrete, tangible result. See e.g., States Street Bank & Trust Co. v. Signature Financial Group Inc., 47 USPQ2d 1596 (Fed. Cir. 1998); AT&T Corp. v. Excel Communications Inc., 50 USPQ2d 1447 (Fed. Cir. 1999). Under that test, the invention must have practical utility, it must produce an assured result, and it must not be merely an abstraction lacking in physical substance. The invention must achieve a practical application having real world value of immediate benefit to the public.

In this case, the claimed invention does not produce a “concrete” result in the sense that it cannot be reasonably assured that dysfunction would in fact be definitively managed or that healing in any scientifically measurable way would be achieved by following the steps of the method. There is simply too much subjectivity involved

because the method effectively relies on subjective criteria rather than objective standards. Actual enablement of pain management and healing is speculative and the method itself is no more than an attempt and a hoped-for result.

Claims 1-9 do not produce a concrete result in the technological arts. The invention as disclosed and claimed does not promote the progress of the useful arts. Accordingly claims 1-9 do not define statutory subject matter. The repeatability of the method is not assured, the results are only hoped for. The method applied to different patients having the same malady may or may not produce the same results. Even further, the actual method applied to two patients having the same malady may or may not be the same because the actual pathway statement used in the method is determined by the particular practitioner. Because the method itself is generated by each individual practitioner (while forming the pathway statement) the results may or may not be the same as set forth in the specification. Without a concrete, specific method, a concrete result cannot be obtained.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The utility requirement under Section 101 requires that any asserted utility be substantial, specific, and credible. Here, the asserted utility is not. The disclosure asserts utility for pain management and healing as a general goal only, and, it is more likely than not that those skilled in the medical art would doubt or question the truth of

the asserted utility. No credible scientific publications or other evidence have been offered or have been uncovered that would tend to establish, more likely than not, that the utility asserted would in fact be achieved. It is not logical, scientifically or technologically, that the steps of the method claimed would be the actual cause of either pain management or healing. The applicant has supplied a plurality of declarations and statements to support the utility of the claimed method. Each of these has been considered and will be addressed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as directed to subject matter not described in such a way as to enable one skilled in the art to use the invention. Because the invention lacks a substantial, specific, and credible utility as set forth above, one skilled in the art clearly would not know how to use the claimed invention without undue experimentation. See MPEP 2107.01, IV.

Realizing that an applicant's disclosure enjoys a certain presumption of enablement, an analysis of the so-called Wands factors (MPEP 2164.01, 2164.01(a); In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988)) rebuts the presumption. The nature of the invention is one that immediately suggests a speculative rather than a documented scientific endeavor. The prior art does not present any credible scientific evidence of

related processes achieving the asserted result. There is virtually no reliable predictability as to outcome based on such a method. The particular direction given by the inventor to achieve the result is general and widely alternative in nature. There are no actual scientifically conducted working examples of the process achieving the asserted results. The quantity of experimentation necessary to use the invention to the end stated looms large given the speculative nature of the invention. Accordingly, enablement is not established by the disclosure sufficient to meet the "more likely than not" standard. The method is based on forming and using pathway statements, however the metes and bounds of what would be a functioning pathway statement has not been set forth. The specification sets forth examples of pathway statements however without undue experimentation a practitioner would not know what is a functioning pathway statement, outside of the examples set forth, without undue experimentation.

Further, as indicated in the declarations and statements provided by the applicant and as found on the internet, 6 pages from www.neuromodulationtechnique.com, by Leslie S Feinberg D.C., the applicant provides seminars (including personal training) and seminar manuals for practitioners wanting to use the applicant's method. The seminar manual and seminar training is different from the applicant's specification by the applicant's own admission, see applicant's declaration. The statements and declarations do indicate that the seminar manual and seminars themselves are enabling. However, none of the declarations or statements set forth that the applicant's specification and claims are enabling. Also, the applicant's

own web page from 8/31/2002, page 4, first full paragraph(provided with last office action) the applicant states that "Practitioners will leave the seminar with the confidence and competence to use this powerful work immediately on return to their practices. We won't just talk about what NMT can do; we will show you. We will walk you through this work until you are comfortable using it,...", this leads the examiner to take the position that the seminar manuals or specification alone are not enabling. If practitioners of ordinary skill in the art require personal training and "walked through" the material then the material is not enabling.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Omura (5,188,107).

Omura teaches using muscle response testing (other than conscious to other than conscious level). Omura does not specifically set forth forming a pathway statement, and interrogating the subject, it is the examiner's position that in performing the method as disclosed by Omura the practitioner would inherently form a pathway statement and interrogate the patient before performing the bi-digital o-ring test as the patient is tested for different organs or cancers as described in the specification. To

help the patient understand the testing such an explanation must be presented when switching between test slides as described. The examiner is taking the interaction between the patient and practitioner as a semantic algorithm.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by 6 pages from www.neuromodulationtechnique.com, by Leslie S Feinberg D.C.. The web pages have been archived to 08/31/2002, see webpage from internet archive wayback machine. See specifically pages 2 and 3, "How was NeuroModulation Technique Developed?" which sets forth the claimed method steps.

The applicant argues that the internet publication is not enabling and fails to disclose the methodology. The document need not be enabling when the claimed method steps are set forth. The applicant's attention is directed to pages 2 and 3, "How was NeuroModulation Technique Developed?" which sets forth the claimed method steps.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ebaugh, statement 13 supplied by the applicant. The statement indicates that Daniel Ebaugh has been using NMT for 2 and one half years prior to signing the statement. The statement was dated 1/12/2005. Therefore, Ebaugh would have been using NMT prior to 9/15/2002.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Adams, statement #9 supplied by the applicant. The statement indicates that Daniel Ebaugh has been using NMT for 2 and one half years prior to signing the statement. The statement was dated 1/24/2005. Therefore, Ebaugh would have been using NMT prior to 9/15/2002.

Response to Amendment

All statements and declarations under 37 CFR 1.132 filed 1/10/2005, 1/12/2005, and 2/24/2005 are insufficient to overcome the rejection of claims 1-9 based upon utility and enablement as set forth in the last Office action because: None of the statements or declarations indicate that the applicants specification and claims have been reviewed and are enabling or has utility. The statements and declarations do indicate that the seminar manuals and teachings at the seminars where enabling. The applicants own declaration indicates that the applicant's specification is a "effective condensation". Therefore the specification is not the same as the manual used for teaching and the applicant's seminars. Further, the applicant indicates the he has taught others using the NMT seminar manual. Because this subject matter is taught, it is the examiner's position that the manual itself is not enabling but requires the inventor's instruction to be learned, understood and practiced.

Further, none of the statements or declarations set forth exactly the method used only a broad statement of an NMT method was used.

Also, none of the case studies were performed under controlled circumstances. No scientific studies were set forth. Some of the statements and declarations indicate combined therapies were used, at least Ferrazzano and Dietz, therefore making the methodology used unclear.

The applicant argues that Omura is different from the disclosed method of the applicant. This may be the case in that Omura is a "vial type" method and the applicants disclosed method is not "vial type", however the rejected claims do not set forth any such differences.

Conclusion

Applicant's amendment necessitated the new ground(s)(statements and declarations filed by applicant) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenberg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Samuel G. Gilbert
Primary Examiner
Art Unit 3736

sgg